UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,550	06/28/2001	Albert Collinson	BBC-083 A US	6240

7590 05/09/2005

KENNETH P. ZWICKER
ABBOTT BIORESEARCH CENTER
100 RESEARCH DRIVE
WORCESTER, MA 01605

EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,550	COLLINSON ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-95* is/are pending in the application.

4a) Of the above claim(s) *5-8,11 and 32-88* is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *1-3,12-31 and 89-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 2 February 2005 is acknowledged. Claims 1-8 and 11-95 are pending in this application. Claims 5-8, 11 and 32-88 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejections of claims 1-4, 9, 12-14, 16, 28, 29, 31, and 89 under 35 U.S.C. 103(a) as being unpatentable over Luger et al., Immunobiology, 1986, vol. 172, pp. 346-356, in view of Green, J. Immunological Methods 1999, Vol. 231, pp. 11-23, of claims 1-4, 9, 12-14, 17, 28, 31, and 89 as unpatentable over Luger et al. in view of Nguyen et al., Microbiol Immunol. 1997, vol. 41(12), pp. 901-907, of claims 1-4, 9, 12-14, 18, 28, and 31 as unpatentable over Luger et al. in view of Reisner et al., Tibtech, 1998, vol. 16, pp. 242-246, of claims 1-4, 9, 12-14, 19, 20, 24, and 31 as unpatentable over Luger et al. in view of Barbas et al., Proc. Nat. Acad. Sci. 1991, vol. 88, pp. 7978-7982, of claims 1-4, 9, 12-14, 19, 21, and 31 as unpatentable over Luger et al. in view of WO 99/36569, Wittrup et al., 1999, of claims 1-4, 9, 12-14, 19, 21, 22, and 31 as unpatentable over Luger et al. in view of WO 98/49286, Iverson et al., 1998, of claims 1-4, 9, 12-14, 19, 23, and 31 as unpatentable over Luger et al. in view of WO 98/31700, of claims 1-4, 9, 12-14, 25, and 31 as unpatentable over Luger et al. in view of U.S. patent 5580717, Dower et al., 1996, of claims 1-4, 9, 12-14, 26, and 31 as unpatentable over Luger et al. in view of WO 9729131, Salfeld et al., 1997, of claims 1-4, 9, 12-14, 27, 31, and 95 as unpatentable over Luger et al. in view of Babcock et al., Proc. Nat. Acad. Sci., 1996, vol. 93, pp. 7843-7848, and of claims 1-4, 9, 12-14, 29, 30, 31, and 90-94 as unpatentable over Luger et al. in view of Knappik

et al., JMB, Feb. 2000, vol. 296, pp. 57-86 are withdrawn in view Applicant's amendment to claim 4, cancellation of claim 9, and the new rejections under 35 U.S.C. 103(a) set forth below. Applicant's arguments are addressed below as they pertain to the new rejections.

3. The rejection of claims 4 and 9 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims is withdrawn in response to Applicant's amendment to claim 4 and cancellation of claim 9.

Claim Rejections Maintained/New Grounds of Rejection

3. Claims 1-3, 12-14, 16, 28, 29, 31, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luger et al., Immunobiology, 1986, vol. 172, pp. 346-356, in view of U.S. patent 6,036,978 (Gombotz et al., priority date 1994), further in view of Green, J. Immunological Methods 1999, Vol. 231, pp. 11-23.

Luger et al. teaches a monoclonal antibody that reacts with and inhibits the activity of both interleukin 1α and interleukin 1β. See p. 354. Luger et al. concludes that this antibody binds to a shared epitope of interleukin 1. Thus, Luger et al. teach an antibody that reacts with and inhibits IL-1α and β, as specified in claims 1-3 and 31. The antibody was generated in mice using a common structural feature of the two molecules, as specified in claims 4 and 12-14. Luger et al. further teaches that IL-1 is involved in inflammatory disease (pp. 346 and 354) and states that this involvement is the rationale for developing the antibody and would be useful to investigate the role of IL-1 during inflammatory disease (abstract, p. 346).

Luger et al. fails to explicitly teach a therapeutic use of this antibody. The '978 patent teaches therapeutic compositions of monoclonal antibodies that react with IL-1 in column 3,

lines 11-20. The '978 patent particularly teaches in column 4, lines 11-21 that the antibody taught by Lugar is useful for this purpose.

Luger et al. and the '978 patent fail to teach the use of transgenic mice for the production of human antibodies or other means of producing antibodies that are not fully mouse. Green teaches XenoMouse™ strains, which are transgenic mice that generate human antibodies (see abstract). Green teaches that there are disadvantages to murine antibodies (p. 12, column 1) and that chimeric antibodies have been used to overcome these disadvantages (p. 12, column 2). Green further teaches that the disadvantages of murine antibodies are overcome by using XenoMouse™ strains to generate antibodies (p. 20, column 1). Green fails to teach the use of these mice to generate antibodies against IL-1 or the use of chimeric anti-IL-1 antibodies. However, it would have been obvious to one of ordinary skill in the art to combine the teachings of Green with those of Luger et al. and the '978 patent to produce humanized IL-1 antibodies or to produce chimeric antibodies. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable, and Green teaches methods of making a more useful form of such an antibody. Thus one of ordinary skill would expect to be able to produce a superior monoclonal antibody for use in inhibiting the effects of IL-1 in inflammation using the approaches set forth by Green.

4. Claims 1-3, 12-14, 17, 28, 31, and 89 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al. in view of the '978 patent and further in view of Nguyen et al., Microbiol Immunol. 1997, vol. 41(12), pp. 901-907.

Luger et al. and the '978 patent teach as set forth above but fail to teach SCID mice reconstituted with human cells or other means of producing antibodies that are not fully mouse.

Nguyen et al. teaches that such mice are useful for the production of human monoclonal antibodies and teaches the advantages of such antibodies (p. 901, column 1, p. 905, column 2, p. 906, column 1). Nguyen fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of Nguyen et al with those of Luger et al. and the '978 patent to produce human IL-1 antibodies. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable, and Nguyen et al. teaches a method of making a more useful form of such an antibody. Thus one of ordinary skill would expect to be able to produce a superior monoclonal antibody for use in inhibiting the effects of IL-1 in inflammation.

5. Claims 1-3, 12-14, 18, 28, and 31 are rejected under 35 U.S.C. (a) as unpatentable over Luger et al.in view of the '978 patent and further in view of Reisner et al., Tibtech, 1998, vol. 16, pp. 242-246.

Luger et al. and the '978 patent teach as set forth above but fail to teach irradiated mice protected by bone marrow cells of SCID mice and engrafted with human lymphocytes or other means of producing antibodies that are not fully mouse. Such mice are taught by Reisner et al. Reisner et al. further teaches that these mice can be used for generating human monoclonal antibodies (p. 242, column 2, p. 243, p. 244) and that such antibodies are useful therapeutically (p. 243). Reisner et al. fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of Reisner et al. with those of Luger et al. and the '978 patent to produce human IL-1 antibodies. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and Reisner et al. teaches a method of making a more useful form

of such an antibody. Thus one of ordinary skill would expect to be able to produce a superior monoclonal antibody for use in inhibiting the effects of IL-1 in inflammation.

6. Claims 1-3, 12-14, 19, 20, 24, and 31 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al. in view the '978 patent and further in view of Barbas et al., Proc. Nat. Acad. Sci. 1991, vol. 88, pp. 7978-7982.

Luger et al. and the '978 patent teach as set forth above but fail to teach combinatorial antibody libraries or the expression of such libraries on phage surfaces, as claimed in claim 20, or other means of producing antibodies that are not fully mouse. Barbas et al. teaches display of combinatorial antibody libraries on the surface of phage M13 and teaches the use of the use of such libraries to generate antitetanus toxoid antibodies on p. 7980. The library used was an Fab library (see abstract and p. 7979, column 1), as specified in claim 24. Barbas et al. further teaches that such methods are useful for selection of clones of defined specificity and high affinity (p. 7981). Barbas et al. fails to teach antibodies against IL-1. However, it would have been obvious to one of ordinary skill in the art to combine the teachings of Barbas et al. with those of Luger et al. and the '978 patent to produce antibodies against IL-1 using phage display. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and Barbas et al. teaches a superior method of making such antibodies.

7. Claims 1-3, 12-14, 19, 21, and 31 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al. in view of the '978 patent and further in view of WO 99/36569, Wittrup et al., 1999.

Luger et al. and the '978 patent teach as set forth above but fail to teach combinatorial antibody libraries or their display on yeast cells, as claimed in claim 21, or other means of producing antibodies that are not fully mouse. WO 99/36569 teaches such yeast selection systems and teaches on pp. 20-21 that these systems are particularly suited for antibodies. WO 99/36569 fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of WO 99/36569 with those of Luger et al. to produce antibodies against IL-1 using display on yeast cells. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and WO 99/36569 teaches a superior method of making such antibodies.

8. Claims 1-3, 12-14, 19, 21, 22, and 31 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al. in view of the '978 patent and further in view of WO 98/49286, Iverson et al., 1998.

Luger et al. and the '978 patent teach as set forth above but fail to teach recombinant antibody libraries or their display on yeast cells, as claimed in claim 21, or bacterial cells, as claimed in claim 22, or other means of producing antibodies that are not fully mouse. WO 98/49286 teaches expression libraries for antibodies and their expression on yeast cells on p. 5, line 7 and on bacterial cells on p. 5, lines 20-31, for example. WO 98/49286 teaches that this system is advantageous because it allows for rapid and efficient selection, purification, and screening (p. 13, lines 29-31 and p. 14, lines 1-5). WO 98/49286 fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of WO 98/49286 with those of Luger et al. and the '978 patent to produce antibodies against IL-1 using display on yeast cells. One of ordinary skill would be motivated to do so because the '978

patent teaches that pharmaceutical compositions of the Luger antibody are desirable and WO 98/49286 teaches a superior method of making such antibodies.

9. Claims 1-3, 12-14, 19, 23, and 31 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al.in view of the '978 patent and further in view of WO 98/31700.

Luger et al. and the '978 patent teach as set forth above but fail to teach RNA-protein fusions as claimed in claim 23 or other means of producing antibodies that are not fully mouse. WO 98/31700 teaches such fusions and teaches that they can be used to improve human or humanized antibodies on p. 64, lines 18-29, and p. 65, lines 1-7. WO 98/31700 fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of WO 98/31700 with those of Luger et al. and the '978 patent to produce antibodies against IL-1 using display on yeast cells. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and 98/31700 teaches a superior method of making such antibodies.

10. Claim 1-3, 12-14, 25, and 31 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al.in view of the '978 patent and further in view of U.S. patent 5580717, Dower et al., 1996.

Luger et al. and the '978 patent teach as set forth above but fail to teach *in vitro* screening as claimed in claim 23 or other means of producing antibodies that are not fully mouse. The '717 patent teaches such a method; see column 4, lines 2-41. The '717 patent further teaches that this is a useful method for screening large libraries and that this advantage is particularly significant for antibodies in column 1, lines 28-50. The '717 patent fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the

teachings of the '717 patent with those of Luger et al. and the '978 patent to produce antibodies against IL-1 using a recombinant antibody library prepared from immunized animals. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and '717 patent teaches a method that allows the screening of large numbers of such antibodies.

11. Claim 1-3, 12-14, 26, and 31 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al. in view of the '978 patent and further in view of WO 9729131, Salfeld et al., 1997.

Luger et al. and the '978 patent teach as set forth above but fail to teach *in vitro* maturation or other means of producing antibodies that are not fully mouse. WO 97/29131 teaches the generation of high-affinity TNF-α antibodies using this approach: see pages 18-21. WO 97/29131 further teaches that these antibodies are neutralizing, bind with high affinity, and have slow dissociation kinetics. WO 97/29131 fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of WO 97/29131 with those of Luger et al. and the '978 patent to produce antibodies against IL-1 using *in vitro* maturation. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and WO 97/29131 teaches a method that produces antibodies with the desirable characteristics of high affinity, slow dissociation, and neutralization.

12. Claim 1-3, 12-14, 27, 31, and 95 are rejected under 35 U.S.C. 103(a) as unpatentable over Luger et al. in view of the '978 patent and further in view of Babcock et al., Proc. Nat. Acad. Sci., 1996, vol. 93, pp. 7843-7848.

Luger et al. and the '978 patent teach as set forth above but fail to teach selection of single cells and recovery of variable regions or other means of producing antibodies that are not fully mouse. Babcock et al. teaches this method: see, for example, the discussion section on pp. 7847-7848. Babcock et al. further teaches that this method can be used to produce antibodies with specific characteristics (p. 7847, column 1) and would be particularly useful for the generation of humanized antibodies for medical applications (p. 7848, column 1). Babcock et al. fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to combine the teachings of Babcock et al. with those of Luger et al. and the '978 patent to produce antibodies against IL-1 using the method of Babcock et al. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and Babcock et al. teaches a method that produces antibodies with particular characteristics and is particularly useful for producing humanized antibodies for therapeutic use.

13. Claims 1-3, 12-14, 29, 30, 31, and 90-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luger et al. in view of the '978 patent and further in view of Knappik et al., JMB, Feb. 2000, vol. 296, pp. 57-86.

Luger et al. and the '978 patent teach as set forth above but fail to teach chimeras or CDR-grafted antibodies or other means of producing antibodies that are not fully mouse. Knappik et al. teaches chimeric antibodies as a useful alternative to purely rodent antibodies on p. 58, column 1. Knappik et al. further teaches generation of CDR-grafted antibodies as a means of generating high affinity binders; see the abstract, for example. Knappik et al. fails to teach antibodies against IL-1. However, it would be obvious to one of ordinary skill in the art to

combine the teachings of Knappik et al. with those of Luger et al. and the '978 patent to produce chimeric or CDR-grafted antibodies against IL-1. One of ordinary skill would be motivated to do so because the '978 patent teaches that pharmaceutical compositions of the Luger antibody are desirable and Knappik et al. teaches methods that produce antibodies that avoid the difficulties associated with therapeutic use of rodent antibodies.

14. As stated above, Applicant's arguments are addressed as they pertain to the new rejections.

Applicant reiterates the legal standard for obviousness on pp. 14-15. Applicant argues that Lugar does not teach or suggest the use of transgenic mice, SCID mice, or other forms of generating not fully mouse antibodies. Applicant argues that the secondary references cited by the examiner do not teach the antibody taught by Luger.

Applicant cites in re Dembiczak and argues that the examiner has failed to show "evidence" of teaching, suggestion, or motivation to combine the references. Applicant argues that the examiner has provided a "broad conclusory statement" that one of ordinary skill would expect to be able to produce a superior monoclonal antibody. Applicant argues that Luger states only that the monoclonal antibody would be useful to investigate the role of IL-1 in disease. Applicant continues to argue that Luger does not provide motivation to produce a dual specificity antibody.

Applicant cites Cardiac Pacemakers Inc v. St. Jude Medical as holding that a combination of know methods was not obvious because recognizing the problem does not render obvious to eventual solution. Applicant argues that the cited art does not teach that IL-1 is a potential

therapeutic target, that an antibody would be a useful therapeutic [agent], that the antibody is a dual-specificity antibody, and that the antibody is not fully murine.

Applicant cites Ruiz v. A.B.Chance and states that the instantly cited references do not teach the problem to be solved, since the references make no mention of treating IL-1 mediated diseases.

Applicant's arguments have been fully considered but have not been found to be persuasive.

With reference to Applicant's arguments against the references individually, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As was stated in the office actions of 31 December 2002, 7 October 2003, and 2 August 2004, the advisory action of 4 May 2004, and the interview summaries of 22 December 2003 and 9 December 2004, Luger teaches a dual specificity antibody that binds to both IL-1α and IL-1β. Luger also teaches that IL-1 is involved in inflammatory disease. See the first sentence of the abstract: "Cytokines exhibiting interleukin 1 activity are known as important mediators of immunity and inflammation." Luger recognizes the importance of inhibition of interleukin 1. See the second sentence of the abstract: "Therefore (emphasis added) the ability of a monoclonal anti IL-1 antibody to neutralize and bind IL-1 was investigated." The newly cited reference, U.S. patent 6,036,978, specifically teaches what would be clear to the artisan of ordinary skill on reading Luger: that this antibody has a therapeutic use in the treatment of inflammation. The

'978 patent teaches compositions with improved therapeutic characteristics and points particularly to the antibody of Luger as being "suitable for use in this invention" (column 4, lines 12-13). Thus, clearly, the artisan would recognize that this antibody was useful therapeutically and would be motivated to modify it in ways well known in the art to improve the pharmaceutical usefulness of antibodies. In addition, as has been stated previously, no motivation is required to make a dual specificity antibody. Luger et al. made such an antibody. The motivation required is to modify it to make it not fully mouse. The role of IL-1 in inflammation taught by Luger and the explicit teachings of the '978 patent that the antibody has a therapeutic use provide the motivation to modify it. The artisan would expect to be successful for the same reasons Applicant does, that techniques for modifying antibodies are well known in the art, as evidenced by the secondary references provided by Applicant.

15. The rejection of claims 1-3, 12-31, and 89-95 are under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for not fully mouse versions of the antibody characterized by Luger et al. and Kock et al. (J. Exp. Med., 1896, vol. 163, no. 2, pp. 463-468), as well as those generated by SEQ ID NO 3, does not reasonably provide enablement for all dual-specificity antibodies and means of making them, is maintained for reasons of record in the office actions of 31 December 2002, 7 October 2003, and 2 August 2004, the advisory action of 4 May 2004, and the interview summaries of 22 December 2003 and 9 December 2004.

Applicant argues that claims 1-3 are not limited by any means of making the antibody and that "the examiner has acknowledged that Applicants' not fully mouse dual-specificity antibody is enabled". Applicant notes that claim 4 is now limited SEQ ID NO: 3 and that claims 9 and 10 are cancelled.

Applicant's arguments have been fully considered but have not been found to be persuasive. As has been stated in the previous office actions, antibodies generated by SEQ ID NO: 3 and the antibody of Luger and Kock are enabled. However, the instant claims 1-3, 12-31, and 89-95 encompass all antibodies that are dually specific for IL-1α and IL-1β. Applicants have provided one epitope that will generate such an antibody. Lugar and Kock have provided one antibody with the desired property. Applicants have shown that three other epitopes were not useful for the generation of an antibody with this unusual property. Neither Applicant nor the prior art teaches any common properties shared by the sequence provided by Applicant and the epitope responsible for the generation of the antibody of Luger and Kock. Thus, neither Applicant nor the prior art describes a genus of epitopes that will produce antibodies with the desired properties, and the artisan would not be able to make dual specificity antibodies as broadly claimed by Applicant. Only two epitopes, one of which (that of Kock and Luger) is not characterized, are known and, since the required features of these epitopes that produce antibodies with the unusual property of reacting with both IL-1α and IL-1β are thus not provided, it would require undue experimentation for the artisan to discover these characteristics and thus be able to make Applicant's invention as broadly claimed.

CLAIM 4 IS ALLOWED. CLAIMS 1-3, 12-31, AND 89-95 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
28 April 2005

JANET ANDRES
PRIMARY EXAMINER